DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 120-133,140-144, and 153-178 are rejected under 35 U.S.C. 102(e) as being anticipated by Whayne et al.-5865791.

Whayne et al. disclose a method of closing and occluding an LAA using an expandable mesh device 95. As disclosed in col. 11 lines 5-26 and col. 12 lines 10-60, the mesh can either be placed over the inverted LAA or placed in the LAA or can be placed over the sack entrance to prevent thrombus from moving from the pouch into the atrium. The device is placed by a delivery catheter through a guiding catheter. The mesh can be used in conjunction with an anchoring member. See col. Col. 10 lines 45-67 and fig. 27. The expandable mesh when placed in the LAA or over entrance of the LAA extends across at least some portion of the longitudinal axis atrial appendage even if just a small portion.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 134-139 and 145-152 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whayne et al.-'791.

Whayne et al. disclose the invention as claimed with the exception of the device conforming to the inside wall of the LAA. However, as the mesh self-expands, and since it blocks thrombus from leaving the LAA and since it acts as a support for the LAA, it would have been obvious to have used a mesh of a large enough size to occupy the LAA (and thus contact and conform to the inner wall of the LAA) so that the pouch would not unnecessarily move during heart contractions or blood flow.

6. Claims 1-5 and 38-50, 55-61, 63, 64, 66-71, 85-91, 179, and 180 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cottenceau et al (US 5,375,612) in view of Whayne et al.

Cottenceau et al. dislcose providing a deployment catheter having an elongate flexible body with a proximal and distal end, an implantable device removably carried by the distal end, said device comprising a radially expandable from a reduced diameter to an enlarged diameter configured to conform to an inside surface of the of the left atrial appendage; enlarging the device, wherein the barrier extends across the opening and circumferentially seals against the inside surface. Cottenceau et al. fail to disclose positioning at least a portion of the device in the left atrial appendage. Whayne et al.

disclose positioning a mesh at the opening of a left atrial appendage to prevent thrombus from moving into the artium. Therefore, it would have been obvious to one of ordinary skill in the art to have positioned the device of Cottenceau et al. at the opening of the left atrial appendage to occlude the left atrial appendage and provide additional support to the LAA while preventing thrombus movement as suggested by Whayne et al.

Regarding claims 2-4, 38-40,45-48, 59, and 61 Cottenceau et al. disclose a self expandable frame (7) connected to a porous mesh barrier (9) and having anchoring elements which engage the tissue wall to hold the barrier adjacent the opening and prevent the passage of embolic material.

Regarding claim 41, Cottenceau et al. fails to disclose the pore size. However, one skilled in the art would have recognized that the pore size would have been obvious in order to prevent smaller particles from entering the bloodstream from the LAA.

Regarding claim 42, To have used e-PTFE would have been obvious as one skilled in the art at the time of the invention would have found this material advantageous for this particular application due to its inherent characteristic of have internodal distances in the range necessary to perform a filtering function. It also would be expandable and flexible enough to perform the disclosed function of the mesh.

Regarding claims 50, 55, 64, and 91, Cottenceau et al. fails to disclose the device at least partially blocks passage of embolic material from the atrial appendage by supporting tissue growth. However, it is well known that porous mesh materials support tissue growth. It would have been obvious to one of ordinary skill in the art that the mesh should support tissue growth because it would be advantageous to promote the closure of the atrial appendage for further blocking the passage of embolic material.

Regarding claims 66-71, 86, and 87, To have delivered the mesh by catheter trans-septally would have been an obvious method step to perform as access to the heart as commonly achieved in this manner. To have collapsed the frame into a catheter outside of the body and to have then deployed the device by expanding the device upon the application of an axial force from a plunger extending through the catheter would have been obvious method steps in deploying any self expandable device.

Terminal Disclaimer

7. The terminal disclaimer filed on 9/27/2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 6,152,144 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Response to Arguments

8. Applicant's arguments with respect to claims 1-5 and 38-43, 45-50, 55-61, 63, 64, 66-71, and 85-91 have been considered but are moot in view of the new ground(s) of rejection.

9. Applicant's arguments filed 4/04/07 with respect to new claims 120-178 have been fully considered but they are not persuasive. Rule 37 CFR 1.111(b) requires that applicant MUST "distinctly and specifically point out errors" in the examiners action. Also, arguments or conclusions of an attorney cannot take the place of evidence. In re Cole, 51 CCPA 919,326 F.2d 769, 140 USPQ 230 (1964); In re Schulze, 52 CCPA 1422, 346 F.2d 600, 145 USPQ 716 (1965); Meitzner v. Mindick, 549 F.2d 775, 193 USPQ 17 (CCPA 1977).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER L. HORNBERGER whose telephone number is (571)270-3642. The examiner can normally be reached on Monday through Friday from 8am-5pm, Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. L. H./

Examiner, Art Unit 3734

jlh
4/10/08

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731